K021955

OCT 0 8 2002

June 11, 2002

Subject: **510(k) Summary** of Safety and Effectiveness Information for the Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories.

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992 as part 807.92.

Submitter: Datex-Ohmeda, Inc
1215 West Century Drive
Louisville, CO

Contact: Michael A. Chilbert, Ph.D., P.E.
Phone: 608-221-1551 Fax: 608-223-2496

Proprietary: Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories
Common: Pulse Oximeter, Ear Oximeter
Classification: Oximeter, 74 DQA, 21CFR870.2700, Class II
Ear oximeter, 74 DPZ, 21CFR870.2710, Class II

The Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories are substantially equivalent to the FDA 510(k) cleared and currently marketed Ohmeda 3800 Pulse Oximeter (K962127), the Datex-Ohmeda 3900/3900P Pulse Oximeters (K983684), and the Datex-Ohmeda M-OSAT Pulse Oximeters and Accessories (K011670)

The Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories are designed to measure noninvasive arterial blood oxygen saturation and pulse rate. They can be used for Adult, pediatric or neonatal monitoring in clinical settings and at home.

The Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories were designed to comply with the applicable portions of the following voluntary standards:

EN 475 Medical Devices - Electrically Generated Alarm Signals
EN 865 Pulse Oximeters - Particular Requirements
ISO 9919 Pulse Oximeters - Particular Requirements
EN/IEC 60601-1 Medical Electrical Equipment: General Requirements For Safety
EN/IEC 60601-1-1 Coll. Standard: Safety Requirements For Medical Electrical Systems
EN/IEC 60601-1-2 Coll. Standard: Electromagnetic Compatibility - Requirements & Tests
EN/IEC 60601-1-4 Collateral Standard: Programmable Electrical Medical Systems
CSA 22.2 601.1 Medical Electrical Equipment, Part 1: General Requirements for Safety
UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety

The Datex-Ohmeda 3800/3900/3900P Pulse Oximeters and Accessories has been validated through testing that, in part, support the compliance of the device to the above mentioned standards.

Contact: Michael A. Chilbert, Ph.D., P.E.
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Michael A. Chilbert, Ph.D., P.E.
Manager, Regulatory Affairs
Datex-Ohmeda, Incorporated
Anesthesia and Drug Delivery Business Unit
1315 West Century Drive
Louisville, Colorado 80027

Re: K021955
Trade/Device Name: TruTrak Plus Enhancements to the Datex-Ohmeda 3800 Series & 3900 Series Pulse Oximeter and Accessories
Regulation Number: 21 CFR 870.2700 & 21 CFR 870.2710
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA & DPZ
Dated: September 6, 2002
Received: September 9, 2002

Dear Dr. Chilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021955

Device Name: TruTrak Plus Enhancements to the Datex-Ohmeda 3800 Series and 3900 Series Oximeters and Accessories

Indications For Use:

The Datex-Ohmeda 3800 Series and 3900 Series Oximeters with TruTrak Plus are indicated for spot-checking and continuous monitoring of functional oxygen saturation and pulse rate, including monitoring during conditions of clinical patient motion. These devices are intended for use with adult, pediatric and neonatal patients in both hospital and non-hospital environments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number: _____

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21CFR801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K021955